IX. 510(k) Summary

K051296

SUBMITTER: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Mary E. Gray
Telephone (508) 828-3649
Fax (508) 828-3797

DATE PREPARED: August 12, 2005

CLASSIFICATION NAME: Smooth or threaded metallic bone fixation fastener

PROPRIETARY NAME: SIJF Cannulated Screw System

PREDICATE DEVICES: Stryker Asnis III Cannulated Screws (K000080 and K024060)
ACE Medical Cannulated Screws (K903810)

DEVICE DESCRIPTION: SIJF Cannulated Screws consists of cannulated screws available in titanium in two diameters of 6.5mm and 8.0mm with lengths ranging from 40mm to 50mm, in 2mm increments.

The SIJF System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

INTENDED USE: The SIJF Cannulated Screw is intended for fracture fixation of long bones and of the pelvis for such conditions as degenerative sacroiliitis, trauma (fracture and/or dislocation) or tumor, iatrogenic instability and Osteitis Condensans Iiii. The system is not intended for spinal use.

MATERIALS: Manufactured from ASTM F-136 implant grade titanium alloy.

PERFORMANCE DATA: Performance data were submitted to characterize the SIJF Cannulated Screw components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 7 2011

DePuy Spine, Inc.
% Ms. Mary E. Gray, RAC
Sr. Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K051296
Trade/Device Name: SIJF Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: August 12, 2005
Received: August 15, 2005

Dear Ms. Gray:

This letter corrects our substantially equivalent letter of August 26, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): K051296

Device Name: SIJF Cannulated Screw System

Indications For Use:

The SIJF Cannulated Screw is intended for fracture fixation of long bones and of the pelvis for such conditions as degenerative sacroiliitis, trauma (fracture and/or dislocation) or tumor, iatrogenic instability and Osteitis Condensans Ilii. The system is not intended for spinal use.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K501296